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10/535,092	05/13/2005	Thomas C Kienzle III	14131US02	1923
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/535,092	KIENZLE, THOMAS C
	Examiner	Art Unit
	Salieu M. Abraham	3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 May 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-41 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 May 2005 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/26/2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1– 5, 10, 18 – 23, 26 – 28, 30 – 32 and 39 - 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Pub. No. US 2002/0032380 to Acker (Acker).

In Reference to Claim 1

Acker teaches:

A system for tracking the position of an instrument relative to an area of interest (see abstract), comprising:

a) a first fixator secured to a first point along said area of interest, said first fixator being configured to carry first and second localizing devices; a second fixator secured to a second point along said area of interest, said second fixator being configured to carry said first localizing device; (see figures 3 and 4 and claims 1 and 7)

and

b) a third localizing device positioned proximate a third point along said area of interest, said second point being located proximate said first and third points, said third localizing device communicating with said first localizing device at said second fixator and said second localizing device at said first fixator communicating with said first localizing device at said second fixator such that the position of said second localizing device at said first fixator can be determined relative to the position of said third localizing device proximate said third point, said second localizing device at said first fixator being attachable to said instrument and said first localizing device at said second fixator being attachable to said first fixator such that said first localizing device on said first fixator communicates with said second localizing device on said instrument in order that the position of said second localizing device on said instrument can be determined relative to said first localizing device on said first fixator and to said third localizing device proximate said third point. (see figure 3 and sections 0028-0033)

In Reference to Claim 2

Acker teaches:

The system of claim 1, wherein said first localizing device is an electromagnetic transmitter and said second and third localizing devices are electromagnetic receivers. (see section 0004 and figure 3)

In Reference to Claim 3

Acker teaches:

The system of claim 1, wherein said first, second, and third localizing device are emitters for use in an optical tracking system. (see sections 0003 and 0049)

In Reference to Claim 4

Acker teaches:

The system of claim 1, further comprising a computer system that monitors the communications between said first, second, and third localizing devices and calculates their relative positions. (see figure 3, reference mark 56)

In Reference to Claim 5

Acker teaches:

The system of claim 1, wherein additional localizing devices may be positioned about said area of interest. (see section 0004 and figure 3)

In Reference to Claims 18 and 19

Acker teaches:

(**Re Claim 18**) – A method for extending the operating range of a tracking system using localizing devices, comprising: connecting a first fixator carrying a first localizing device to a first point proximate an area of interest; connecting a second fixator carrying a second localizing device to a second point proximate the area of interest; positioning a

third localizing device at a third point, said second point being located proximate said first and third points; providing said first and third localizing devices in communication with said second localizing device such that the position of said first localizing device relative to said third localizing device may be calculated; removing said first localizing device from said first fixator and attaching said first localizing device to an instrument proximate said area of interest; removing said second localizing device from said second fixator and attaching said second localizing device to said first fixator; and providing said first and second localizing devices in communication with each other such that the position of said first localizing device on said instrument relative to said third localizing device may be calculated. (see figure 3, section 0009, and claims 1-2 and 8-9)

(Re Claim 19) – 19. The method of claim 18, wherein said first and third localizing devices are electromagnetic receivers and said second localizing device is an electromagnetic transmitter. (see figure 3, section 0009, and claims 1-2 and 8-9)

In Reference to Claims 20 - 22

Acker teaches a system and corresponding for extending the spatial operating range of an electromagnetic localizing system and that employ a plurality of fixators and localizing devices all of which intercommunicate and are flexibly configurable/exchangeable between/among each other (per claim limitations; see sections 0028 – 0033).

In Reference to Claim 23

Acker teaches:

The system of claim 22, wherein said second localizing device is an electromagnetic

transmitter and said first, third and fourth localizing devices are electromagnetic receivers. (see figure 3 and sections 0009, 0028-0033)

In Reference to Claim 26

Acker teaches:

The system of claim 22, wherein said first, second, third, and fourth localizing device are emitters for use in an optical tracking system. (see sections 0003, 0028-0033 and 0049)

In Reference to Claim 27

Acker teaches:

The system of claim 22, further comprising a computer system that monitors the communications between said first, second, third, and fourth localizing devices and calculates their relative positions. (see figure 3 and 0029 - 0031)

In Reference to Claim 28

Acker teaches:

The system of claim 22, wherein additional localizing devices may be positioned about said area of interest. (see section 0004)

In Reference to Claim 30

Acker teaches:

The system of claim 22, wherein said second fixator is secured to a patient's body by connectable strap and is configured to carry an electromagnetic transmitter. (see figures 1 and 3 and sections 0009, 0041 and 0050)

In Reference to Claims 31 and 32

Acker teaches the system of claim 22:

(Re Claim 31) - wherein said known relationship between said first and second localizing devices at said first fixator is determined by manufacture of said first fixator. (see figure 2)

Re Claim 32) - wherein said known relationship between said first and second localizing devices at said first fixator is determined by a calibration procedure. (see abstract and section 0008)

In Reference to Claims 39 – 40

Acker teaches:

(Re Claim 39) – A method for extending the spatial operating range of an electromagnetic localizing system comprising the steps of: providing an electromagnetic localizing device with an electromagnetic transmitter and receiver; providing a first surgical instrument with an attached receiver; providing a second surgical instrument with an attached receiver; providing a fixator to which a receiver and a transmitter

attach; determining the position of a receiver attached to the fixator relative to a transmitter attached to the fixator; attaching a receiver to the fixator; determining the position of said first surgical instrument relative to said receiver attached to said fixator; removing said receiver from said fixator; attaching a transmitter to said fixator; determining the position of said second surgical instrument relative to said transmitter attached to said fixator; and determining the position of said first surgical instrument relative to said second surgical instrument. (see abstract, claims 7-9 and sections 0008-009 and 0028 -0033)

(Re Claim 40) - The method of claim 39 wherein the step of determining the position of said first surgical instrument relative to said receiver attached to said fixator comprises the steps of: providing a second fixator with a transmitter; determining the position of said receiver on said first surgical instrument relative to said transmitter on said second fixator; determining the position of said receiver on said fixator relative to said transmitter on said second fixator; and determining the position of said receiver on said first surgical instrument relative to said receiver on said fixator. (see abstract, claims 7-9 and sections 0008-009 and 0028 -0033)

3. Claims 33 - 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Pub. No. US 2002/095081 to Vilsmeier (Vilsmeier).

In Reference to Claim 33

Vilsmeier teaches:

A fixator for use with a surgical tracking system, comprising: a means for attaching a first localizing device; and a means for attaching a second localizing device such that the first localizing device is held in a fixed and known relationship to the second localizing device. (see abstract and figures 2 – 4)

In Reference to Claims 34 -36

Vilsmeier teaches the fixator of claim 33:

(Re Claim 34) - wherein said known relationship between said first and second localizing devices at said fixator is determined by manufacture. (see abstract and figures 2 – 4)

(Re Claim 35) - wherein said known relationship between said first and second localizing devices at said fixator is determined by a calibration procedure. (see abstract and figures 2 – 4)

(Re Claim 36) - The system of claim 35, wherein said calibration procedure comprises the calculation of the positions of said first and second localizing devices by a surgical tracking system. (see abstract and figures 2 – 4)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 6, 10 – 14, 16 - 17, and 24 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2002/0032380 to Acker (Acker) in view of US Pat. No. 6,054,724 to Schmitz (Schmitz)

In Reference to Claim 6

Acker has been shown to teach all of the limitations of claim 1. Acker further describes integrating an x-ray imaging component in order to show the position of a medical tool/instrument in relation to the body of a patient (see section 0005). X-ray imaging systems are well known to include C-arm apparatus. However, Acker fails to explicitly teach the x-ray component as highlighted in bold below:

The system of claim 1, **further comprising a C-arm having an imaging device** and said third localizing device and being positioned proximate said third point, said imaging device taking an image of said area of interest, said third localizing device communicating with said first localizing device such that the positions of said first and second localizing devices can be determined relative to said image.

Schmitz, in the same field of endeavor, discloses a method and device for position detection in x-ray imaging that employs a C-arm (see abstract and figure 1). Schmitz cites that the advantage of his invention is in providing an “exact association of the X-ray image with the object imaged” and that this capability “is very important notably for intraoperative imaging”. (see abstract and figure 1)

Therefore, it would be obvious to one of ordinary skill in the art to include the C-arm apparatus of Schmitz in the system of Acker in order to facilitate intraoperative imaging as taught by Schmitz.

In Reference to Claim 10

Acker in view of Schmitz has been to teach all elements of claim 10 to include: an electromagnetic (EM) surgical instrument tracking system employing a C-arm with imaging device using multiple localizing devices and an image display of the surgical instrument in relation to the patient area of interest (see claim 6 rejection above).

Therefore, Acker in view of Schmitz meets all claim 10 limitations.

In Reference to Claim 11

Acker in view of Schmitz has been to teach all limitations of claim 10. Acker further teaches:

The system of claim 10, further comprising a computer system that monitors the communications between said transmitter and said receivers and calculates their relative positions to each other. (see figure 3 and sections 0030, 0032, and 0038)

Therefore, Acker in view of Schmitz meets all claim 11 limitations.

In Reference to Claim 12

Acker in view of Schmitz has been to teach all limitations of claim 10. Schmitz further teaches:

The system of claim 10, wherein the position of said transmitter on said first fixator can be determined relative to the position of said receiver on said first fixator in order that the position of said transmitter on said first fixator relative to said receiver at said C-arm

may be determined. (see abstract and figure 1)

Therefore, Acker in view of Schmitz meets all claim 12 limitations.

In Reference to Claim 13

Acker in view of Schmitz has been to teach all limitations of claim 10. Acker further teaches:

The system of claim 10, wherein additional transmitters and receivers may be positioned about said patient to communicate with each other. (see sections 0028 and 0030)

Therefore, Acker in view of Schmitz meets all claim 13 limitations.

In Reference to Claims 14 and 16 -17

Acker in view of Schmitz has been to teach all limitations of claim 10. Acker in view of Schmitz further teaches the system of claim 10:

(Re Claim 14) - wherein said C-arm calibrates the position of the receiver at said C-arm relative to the image such that when said transmitter communicates with said receiver at said C-arm, the position of said transmitter relative said image may be calculated.. (see Schmitz abstract, figure 1 and columns 1, lines 61-67 and 2, lines 1-28)

(Re Claim 16) - wherein said second fixator comprises a post and lock spring for

securing said transmitter thereto and connectable straps for externally securing said second fixator to the patient's body. (see Acker sections 0009, 0041 and 0050)

(Re Claim 17) - wherein said first fixator comprises a post and lock spring for securing said transmitter thereto and a connection block for securing said receiver thereto. (see Acker figures 1 and 4 and sections 0041 and 0050)

Therefore, Acker in view of Schmitz meets all claim 14, and 16-17 limitations.

In Reference to Claims 24 – 25

Acker has been shown to teach all claim 22 limitations. However, as discussed earlier, Acker does not specifically disclose a C-arm apparatus, but Schmitz does. Specifically, Schmitz discloses the system of claim 22:

(Re Claim 24) - wherein said first instrument carrying said third localizing device is a C-arm having an imaging device and being positioned proximate said first point, said imaging device taking an image proximate said first point such that the position of said second localizing device at said first fixator can be determined relative to said image. (see abstract and figure 1)

(Re Claim 25) - wherein said second instrument is a C-arm having an imaging device and being positioned proximate said second point, said imaging device taking an image proximate said second point, said fourth localizing device communicating with said second localizing device such that the position of said second localizing device at said first fixator can be determined relative to said image. (see figures 1 and 3 and column 2, lines 1-67)

Therefore, Acker in view of Schmitz meets all claim 24-25 limitations.

6. Claims 7, 9 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2002/0032380 to Acker (Acker) in view of US Pat. No. 6,499,488 to Hunter (Hunter)

In Reference to Claim 7

Acker has been shown to teach all of the limitations of claim 1. Acker also discloses where a fixed localizing device platform may be placed on or next to a structure/area of interest within a patient's body (e.g. indirect localization; see section 0009), but not directly to an anatomical structure of the patient. The localizing device can carry out transceiver functions. However, Acker fails to expressly teach (see bolded text in particular):

The system of claim 1, wherein said **first fixator is rigidly secured to a patient's body by bone screws** and is configured to carry an electromagnetic transmitter and an electromagnetic receiver.

Hunter, in the same field of endeavor, discloses an integrated surgical anchor/localization device for facilitating the tracking of movement associated with an anatomical structure (see abstract column 1, lines 25-30). Among the many benefits of the invention Hunter cites that the invention may be "deployed with relative ease" for noninvasive "pre- and intraoperative" fiducial marking purposes (see column 2, lines 22-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the rigidly secured surgical sensor apparatus of Hunter in the system of Acker in order to "provide a localization system for internal anatomical

structures which may be employed with minimal invasive procedures" as taught Hunter (see column 2, lines 30-34).

In Reference to Claim 9

Acker in view of Hunter has been shown to teach localizing instruments relative to a patient's bone as a means for minimal invasive surgery as discussed above for claim 7. Specifically, Acker in view of Hunter teaches:

A system for localizing instruments relative to a patient's bone comprising:

an electromagnetic localizing device with an electromagnetic field transmitter and an electromagnetic field receiver; (see Acker figure 3)

- a) a fixator for attaching to bone, said fixator being capable of attaching a transmitter and receiver in a fixed and known position relative to one another; (see Hunter abstract)
- b) a first surgical instrument with an attached transmitter; a second surgical instrument with an attached receiver; means for determining the position of the first surgical instrument relative to the fixator with an attached transmitter; means for determining the position of the second surgical instrument relative to the fixator with an attached receiver; (see Acker figure 3) and
- c) means for calculating the position of the first surgical instrument relative to the second surgical instrument. (see Acker figure 3)

Therefore, Acker in view of Hunter meets all claim 9 limitations.

In Reference to Claims 37 – 38

(Re Claim 37)

Acker in view of Hunter has been shown to teach a system for localizing instruments relative to a patient's bone comprising all the claim limitations. (see claim 9 rejection)

(Re Claim 38)

Acker in view of Hunter has been shown to teach all claim 37 limitations. Acker further teaches:

The system of claim 37 wherein said means for determining the position of the second surgical instrument relative to said fixator comprises a second fixator with a transmitter, said transmitter in communication with said receiver attached to said second surgical instrument and with a receiver attached to said first fixator. (see figure 3 and sections 0028 – 0033)

Therefore, Acker in view of Hunter meets all claim 37 and 38 limitations.

7. Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2002/0032380 to Acker (Acker'380) in view of US Pat. No. 6,161,032 to Acker (Acker'032).

In Reference to Claim 8

Acker'380 has been shown to teach all of the limitations of claim 1. Acker'380 further discloses a number of attachment means for securing a second fixator to a patient's body (see section 0009, 0012, 0029 and 0033), but none them specify the limitation as

bolded below:

The system of claim 1, wherein said second fixator is secured to a patient's body by connectable strap and is configured to carry an electromagnetic transmitter.

Acker'032, in the same field of endeavor, discloses an electromagnetic-based sensor system for detecting position and orientation of medical probes within a patient's body (see abstract). The sensor system may be attached to the patient via a strap (see figure 1 and column 6, lines 53-56) and allows the sensors in the system to be used as independently positionable reference assemblies (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the strap for securing a localizing device of Acker'032 in the system of Acker'380 in order to allow customizing of the sensor positioning "to move them to the best possible locations to increase sensitivity of the locating system" as explicitly taught by Acker'032 (see column 2, lines 47-56).

8. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2002/0032380 to Acker (Acker) in view of US Pat. No. 6,054,724 to Schmitz (Schmitz) further in view of US Pat. No. 6,499,488 to Hunter (Hunter)

In Reference to Claim 15

Acker in view of Schmitz has been shown to teach all limitations of claim 10.

However, Acker in view of Schmitz fails to teach:

The system of claim 10, wherein said first fixator is rigidly secured to the patient's body by bone screws.

As discussed earlier (see) Hunter discloses a surgical anchor/localization device

capable of being secured to bone (see claim 7 rejection). Among the many benefits of his invention Hunter cites that the invention may be "deployed with relative ease" for noninvasive "pre- and intraoperative" fiducial marking purposes (see column 2, lines 22-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the rigidly secured surgical sensor for bone apparatus of Hunter in the system of Acker in view of Schmitz in order to "provide a localization system for internal anatomical structures which may be employed with minimal invasive procedures" as taught by Hunter (see column 2, lines 30-34).

9. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pub. No. US 2002/0032380 to Acker (Acker) in view of US Pat. No. 6,054,724 to Schmitz (Schmitz) further in view of Pub. No. US 2002/0150215 to Barnes (Barnes).

In Reference to Claim 41

Acker in view of Schmitz teaches all the limitations of claim 41 (see earlier claim 6,10-14 rejections) with the exception of determining and indicating an error if the positions of localization sensors were not within a certain range of each other in order to better determine the relative positions of two areas of interest.

Barnes discloses a mobile preoperative imaging system and method that provides minimal user interaction in reconciling disparate imaging system areas for improved imaging (see abstract). He cites the benefit of his invention in minimizing image interference, noise producing effects and image sensor misalignments that lead to faulty displays of the area(s) of interest (see abstract, figures 3 and 7-9 and 12 and sections 0037-0039 and 0043).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have included the sensor positional error detection scheme of Barnes in the method of Acker in view of Schmitz in order to facilitate the display of system images with regard to speed and presenting a visible means of indicating system/sensor errors that would result in faulty images as taught by Barnes (see sections 0042-0043).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Acker et al., Anderson et al., Ben-Haim et al., Jascob et al., Jensen et al., and Paltiel et al. have been included because they all teach the use of diagnostic imaging methods and systems which make use of electromagnetic energy for position and orientation tracking of areas of interest in vivo similar in scope to applicant's proposed invention.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Salieu M. Abraham whose telephone number is (571) 270-1990. The examiner can normally be reached on Monday through Thursday 9:30 am - 7:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11/18/07 SA

Brian Caster
SPE 3737